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CE CE 0086

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Caution: US federal law restricts this device to sale by or on the order of a physician.

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PL08-0021 Rev. B 07/09

OSBON
ErecAid® ESTEEM®
VACUUM THERAPY SYSTEM

User Guide

Manual Model

Automatic Model

timm® medical technologies, inc.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Indications for Use

The ErecAid® Esteem® Vacuum Therapy System is intended to artificially produce an erection in males suffering from erectile dysfunction (impotence) in order to facilitate sexual intercourse, or to create and maintain erections by providing arterial (oxygen-rich) blood flow to the penis during recovery from prostatectomy. A vacuum is applied to the penis, causing it to become erect and rigid as blood is drawn into the corpora cavernosa. A constriction ring is then placed on the base of the penis to restrict venous blood flow out of the penis. The device is intended to be used at home or in a doctor's office or clinic.

Osbon ErecAid® Esteem® – Vacuum Therapy System

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Device and Component Patent: #4,378,008; #4,856,498; #5,244,455; #5,306,277; #5,234,402; 5,643,290

Other U.S. and Foreign Patents Pending

Packing List
ErecAid® Esteem® Vacuum Therapy System

Please immediately check to make sure the following components are included in your box:

1 Ea	Easy Carrying Case
1 Ea	DVD – ErecAid® Esteem® Multi-lingual Instructions
1 Ea	User Guide for Osbon ErecAid® Esteem® with Warranty Registration Card
1 Ea	Component Order Form
1 Ea	Quick Start Guide
1 Ea	Inverse Tapered Clear Cylinder with Insert
1 Ea	Osbon Personal Lubricant™
1 Ea	ErecAid® Esteem Manual (or Automatic) Pump Handle
1 Ea	Easy-Action® Ring Loader
1 Ea	.750 Pink Medium "D" High Tension Ring
1 Ea	.750 Beige Medium "C" Standard Tension Ring
1 Ea	.875 Pink Large "B" High Tension Ring
1 Ea	.875 Beige Large "A" Standard Tension Ring

In the event that any of these items are missing, immediately call us at 800-438-8592.

Please remember to immediately **complete and mail in Warranty Registration Card** (located in back of User Guide) **within 90 days of purchase**. The completed Warranty Registration Card will provide you with a limited lifetime warranty, refund options, assistance with orders for accessories and toll-free technical assistance.

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Patient Bill of Rights

This Patient Bill of Rights informs you of your rights prior to receiving services from Timm Medical Technologies, Inc.

Timm Medical Technologies, Inc. treats the patient in a dignified and respectful manner.

Timm Medical Technologies, Inc. respects the patient's right to and need for effective communication.

Timm Medical Technologies, Inc. respects the patient's cultural and personal values, beliefs, and preferences.

Timm Medical Technologies, Inc. respects the patient's right to privacy.

Timm Medical Technologies, Inc. allows the patient to access, request amendment to, and obtain information on disclosures of his or her health information, in accordance with law and regulation.

Timm Medical Technologies, Inc. honors the patient's right to give or withhold informed consent.

Timm Medical Technologies, Inc. protects the patient and respects his or her rights during research, investigation, and clinical trials.

The patient and his or her family have the right to have complaints reviewed by Timm Medical Technologies, Inc.

Timm Medical Technologies, Inc. informs the patient about his or her responsibilities related to his or her care, treatment, or services (Included in order forms and systems manuals.)

Timm Medical Technologies, Inc. informs the patient that they may contact the Joint Commission Office of Quality Monitoring to report any unresolved concerns or complaints related to patient safety and quality of care by either calling (800) 994-6610 or email complaints@jointcommission.org.

User Guide

ErecAid® Esteem® Manual and Automatic Vacuum Therapy System

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Principles of Operation

A human erection is a complex event that involves the brain, hormones, blood vessels, nerves and muscles inside the penis. When these work together properly, the penis fills with blood to produce an elongated and hard erection. In simple terms, an erection is a blood-filling and blood-storing event, which takes place inside a man's penis.

A vacuum pump pulls blood into the penis to produce an erection. A tension ring or band holds the blood in the penis, keeping the erection long enough to have sexual intercourse. When the ring or band is removed, the erection quickly goes away.

Using A Vacuum Therapy Device

Please read the following information carefully before using your ErecAid®. While no serious injury has been reported from proper use of this device, it is still important to observe some simple precautions. If you have any questions, call Timm Medical Technologies, Inc.'s toll free help line at **800-438-8592**.

⚠ *Contraindications*

External vacuum therapy is a proven, safe way to treat Erectile Dysfunction, or impotence. However, some patients should not use the device. These include:

1. Men with a previous history of spontaneous priapism (an erection that lasts more than four hours). This may be extremely painful and may cause permanent damage to the penis.
2. Men who have sickle cell trait or disease, or hypercoagulability (excessive blood clotting) are more likely susceptible to suffer from priapism.
3. Men who have a bleeding disorder or who bruise easily. Use of a vacuum device may cause painful bruising of the penis in these men.

For the general population, there is no inherent or significant risk in properly using a vacuum device. Misuse of the device or tension rings, however, may result in painful or permanent injury to the penis. Users should therefore read and follow instructions very carefully.

⚠ *General Warnings and Precautions*

Caution Talk to your doctor if any complications occur in using this device. Stop using the device if complications continue.

Caution **Do not leave the ring on your penis for more than 30 minutes.** Do not fall asleep wearing the ring. Leaving the ring on too long may damage your penis by keeping blood from flowing into it.

Caution **Allow at least 60 minutes between uses of ErecAid.** Using the rings too often may cause bruising at the base of the penis (where the penis is joined to the body).

1. If you have symptoms of Erectile Dysfunction (not being able to get or keep an erection that allows you to have sex), talk to your doctor before using the ErecAid® to prevent a delay in discovering and treating the cause. Common causes of Erectile Dysfunction are heart disease, diabetes, multiple sclerosis, cirrhosis of the liver, chronic renal failure and alcoholism.
2. Ask your doctor about using the ErecAid if you are taking anti-coagulant (blood-thinning) medicine; if you have a penile implant; or if you have Peyronie's disease, leukemia or other blood disorders where bleeding or clotting may be a problem. The effects of the ErecAid system on the components of implanted penile prostheses have not been adequately investigated. Therefore, if you have a penile prosthesis, consult your physician prior to use.
3. Do not use the vacuum pump under the influence of drugs or alcohol. These substances may reduce your sensitivity to pain or impair your ability to follow directions properly.
4. The vacuum pump may bruise the blood vessels just below the surface of the skin, which may cause tiny reddish spots (petechiae) to appear on your penis. These are not harmful and should disappear with regular use of the device. Bruising may also occur at a deeper level in the penis or scrotum, which could result in hemorrhage (excessive bleeding) and/or hematoma (blood clot).
5. Always use the least amount of vacuum pressure necessary to produce an erection. Using too much pressure or increasing the vacuum pressure too quickly may cause discomfort, pain or bruising. Release vacuum pressure immediately if pain occurs.

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6. Improper use of the vacuum pump could result in the swelling of the penis and/or serious, permanent injury to the penis. Improper use may also worsen pre-existing medical conditions such as Peyronie's disease, priapism and urethral strictures.
7. If you notice a bend or curve in your penis when you first use your ErecAid, talk to your physician.
8. If your hands are impaired, you should not use this product. You must have full use of your hands to safely use the rings and pump. If you do not have enough strength in your hands, you may not be able to remove the ring. Delayed ring removal could damage your penis.
9. The vacuum pump may not be safe for men who cannot feel pain in the area around their penis. If you have diabetes, you may have a reduced ability to feel pain. Pain may be a sign that your penis is being bruised.
10. Tension rings are not a means of birth control. Do not rely on tension rings to avoid pregnancy.
11. Always use the lowest amount of tension necessary to maintain the erection. Start by using the largest size ring with the lowest tension. Add tension, if necessary, by using the next lowest tension level. Do not skip a level when adding tension.
12. After a period of inactivity when the pump has not been utilized, practice sessions will again be necessary to recondition penile tissue prior to resuming sexual activity.
13. If you will not be having sexual activity on a regular basis, you need to continue therapy practice sessions on a regular basis.

ErecAid® Esteem® Vacuum Therapy System

Manual Model

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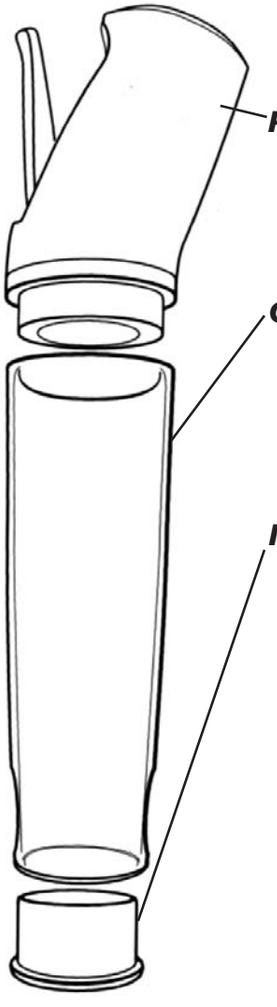
Components – Manual Model

Study the diagram to become familiar with the name and purpose of each part of your new ErecAid Esteem System before you apply the device.



Pump

The manual pump is ergonomically designed to facilitate easy operation to create the proper vacuum.

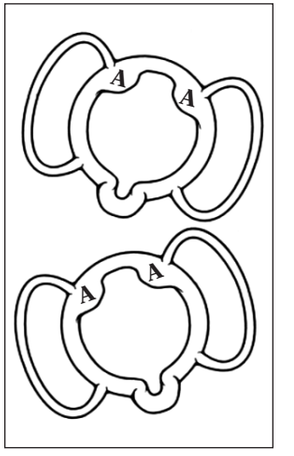
Cylinder

The oval end of the cylinder is designed so you can easily attach the manual pump. The other end of the cylinder fits snugly against your body to help create the vacuum seal.

Insert

The insert may be used to decrease the diameter of the open end of the cylinder, if needed. You should try using the System with and without the insert to decide which way works best for you.

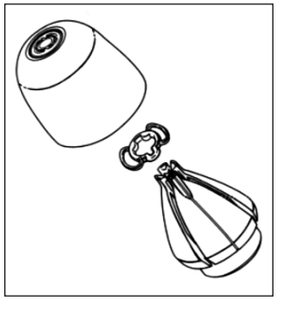
Pressure-Point™ Tension Rings



The patented pressure-point tension rings are medically engineered for safety, performance and comfort. You may use the rings individually or in various combinations to keep your erection once you have created it using the System *(refer to Situation on page 31)*. You will have four pressure-point tension rings packaged with your System: one Medium and one Large ring in standard tension (beige); one Medium and one Large ring in high tension (pink). *See Ring Tension Chart for tension and color details on page 9.*

NOTE: Please note that tension rings are a disposable item and will last 1-6 months or longer, depending on use and storage.

Easy-Action® Ring Applicator



The Easy-Action ring applicator is a specially designed tool that lets you easily load the Pressure-Point tension ring(s) onto your ErecAid Esteem System cylinder.

The Easy-Action ring applicator consists of two parts – a top part, or cap, and a bottom part, or cone.

Lubricant

Osbon Personal Lubricant™ plays an important part in the overall function of the System. Proper application of our water-soluble lubricant to the head of the penis and to the open end of the cylinder helps create a good vacuum seal against the body. The lubricant also helps you to load and remove the tension rings. You should use only water-based Osbon Personal Lubricant. **Other lubricants may damage the tension rings and other System parts, as well as void your limited lifetime warranty.**

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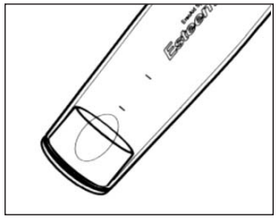
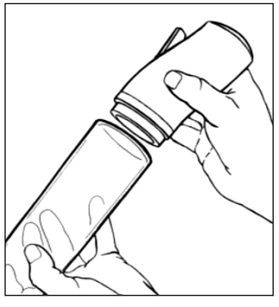
How to Assemble – Manual Model





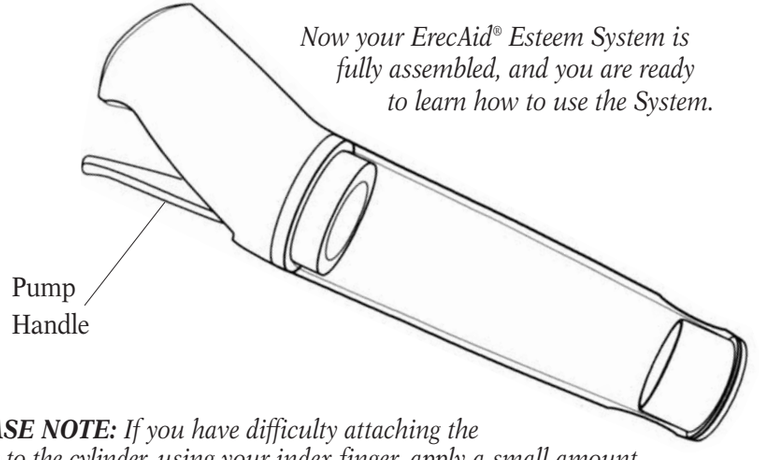
Step 1

Start with the insert in the smaller end of the cylinder, as packaged. The insert narrows the inside of the cylinder and keeps scrotal tissue from being drawn in while you create your erection. If your erection presses uncomfortably against the inside of the insert, remove the insert and use the cylinder without it.

Step 2

Attach the oval end of the pump to the large oval end of the cylinder by pressing them firmly together. Be sure to keep the cylinder's label face up and opposite to the Pump Handle.

Now your ErecAid® Esteem System is fully assembled, and you are ready to learn how to use the System.



PLEASE NOTE: *If you have difficulty attaching the pump to the cylinder, using your index finger, apply a small amount of lubricant to the outer rim of the pump. This will allow the cylinder to connect more easily.* ***Too much lubricant could cause it to seep into and damage the motor.***

Practice Sessions – Manual Model

Practice sessions should be **at least** 10–15 minutes daily for a **minimum** of two weeks.

Before using your ErecAid® System for intercourse, **you must practice** creating an erection. You will be much more satisfied with results by taking the time to complete the practice sessions. Practice sessions help you learn your individual comfort level, the amount of vacuum you need, the best pumping rate for you and the most effective technique for getting a good seal and a firm erection.

Practice sessions also help you understand what to expect from the System, and the sessions can help you become more confident and more satisfied with your sexual experiences.

Most importantly, after a period of sexual inactivity, the vessels in the penis need to become accustomed to being filled with blood again. After a period of inactivity when the pump has not been utilized, practice sessions will again be necessary to recondition penile tissue prior to resuming sexual activity. If you will not be having sexual activity on a regular basis, you need to continue therapy practice sessions on a regular basis. Follow the practice session outlined below, you will provide a slow but steady increase of blood through the vessels of the penis, giving you a better erection.

During your initial practice sessions, **DO NOT** use a tension ring(s). You will only be practicing how to create an erection. Later, when you become comfortable with creating your erection, you will learn how to load and transfer tension rings. Proper use of the tension rings lets you keep a full erection suitable for intercourse.

During practice sessions skip to "How to Create an Erection" on page 12 and also skip over "How to Keep the Erection" on page 14.

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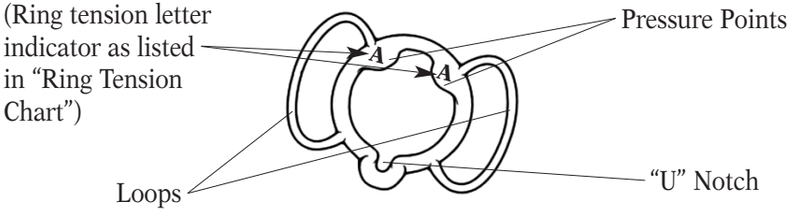
How to Select the Tension Ring

You will need to experiment to find the tension ring that's right for you. Begin with the largest Ring (A) and determine if it is comfortable and provides a satisfactory erection. If not, try the (B) Ring then and then the (C) Ring and then the (D) Ring. **Always try to keep the erection with the least amount of tension. Correct positioning of the tension ring is also necessary to keep the erection.** Tension rings should be positioned so that the "U" shaped notch is on the bottom of the penis and the pressure points are at the top of the penis.

NOTE: When using a combination of rings, the ring with the greatest amount of tension should be closest to your body. See page 31 for instructions on loading and transferring no more than two tension rings.

COLOR CODED TENSION RINGS

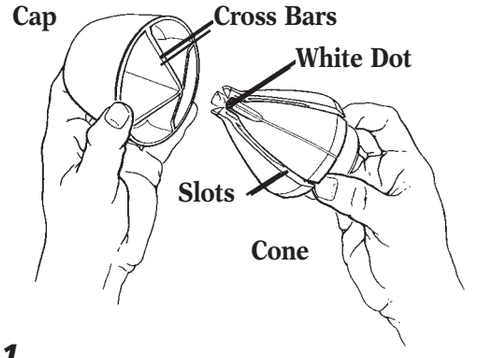
BEIGE	**PINK**
Standard Tension	**High Tension**

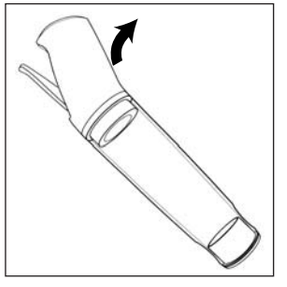


Ring Tension Chart

Minimum Tension	***Level One***	**One large standard-tension ring (beige-A)**
	Level Two	**One large high-tension ring (pink-B)**
	Level Three	**One medium standard-tension ring (beige-C)**
	Level Four	**One medium high-tension ring (pink-D)**
	Level Five	**One medium standard-tension (beige-C) and One large standard-tension ring (beige-A)**
	Level Six	**One medium high-tension (pink-D) and One large high-tension ring (pink-B)**
Maximum Tension	***Level Seven***	**One medium high-tension (pink-D) and One large standard-tension ring (beige-C)**

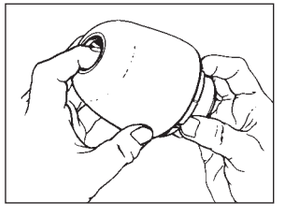
How to Load the Tension Ring Using the Easy-Action® Ring Applicator





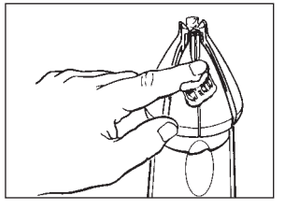
Step 1

Remove the pump and the insert from the cylinder. Put a towel on a table or counter top and stand the cylinder on top of the towel with the large end of the cylinder face down. The towel will keep the cylinder from slipping.



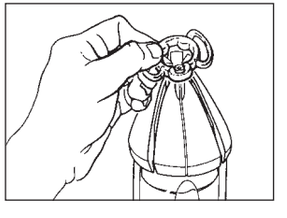
Step 2

Separate the Easy-Action ring applicator by holding the base of the cone in your hand and then pushing the button on the top of the cap. Place the base of the ring applicator cone in the small open end of the cylinder. Twist the cone so that the white dot on top of the cone lines up with the cylinder groove **opposite** the cylinder label.



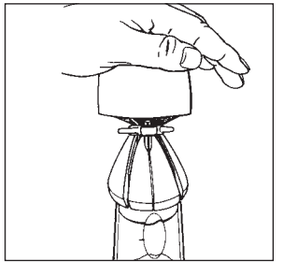
Step 3

Lubricate the entire cone surface with Osbon Personal Lubricant.™



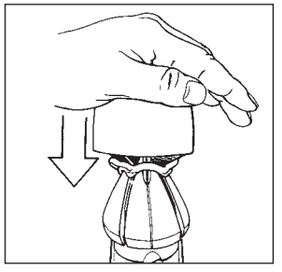
Step 4

Place the tension ring on the cone, making sure to align the **U-notch** on the tension ring with the **white dot** on the cone.



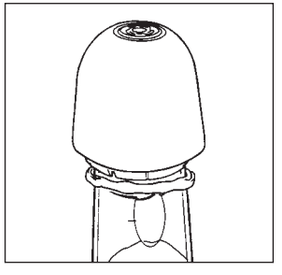
Step 5

Place the cap back on the cone and tension ring, lining up the cross bars of the underside of the cap with the slots on the top of the cone.



Step 6

Then quickly and firmly press straight down on the cap of the ring applicator with one hand while holding the cylinder in an upright position on the towel with your other hand to help stabilize it.



Step 7

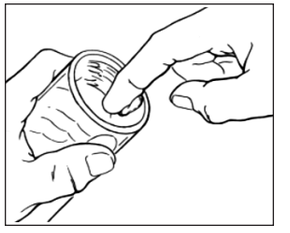
The tension ring should now be transferred to the cylinder in the correct position. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump end of the cylinder to allow space for the additional ring(s). Then, choose another ring and repeat steps 2 through 6.

Step 8

After you have loaded your tension ring(s), remove your ring applicator from the cylinder and replace the insert. Place the pump handle back on to the cylinder. You are now ready to create an erection with your ErecAid® Esteem® System.

How to Create an Erection – Manual Model

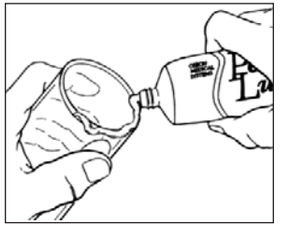
Assemble your System according to the two-step procedure on page 7.



Step 1

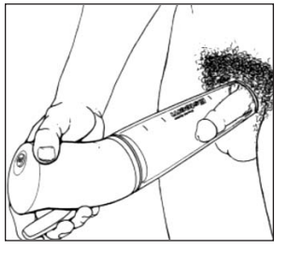
Apply Osbon Personal Lubricant™ to the following:

1. **two inches inside the open end of the cylinder;**
2. **the rim of the cylinder which meets the body to form the vacuum seal; and**
3. **the entire head of the penis.**



Applying lubricant properly will help you achieve the best erection possible.

Tip: *Trimming the pubic hair around the base of the penis with a pair of scissors may also prove helpful in creating an airtight seal.*



Step 2

It is recommended that you stand for this step (the System can also be used when you are sitting or lying down).

Place the lubricated penis inside the cylinder with the label on the cylinder facing up. With one hand, hold the cylinder at a downward 45° angle with the open end snugly against the body.

Tip: *Rotate cylinder slightly back and forth to make an airtight seal against the body, make sure the testicles are not drawn into the cylinder.*

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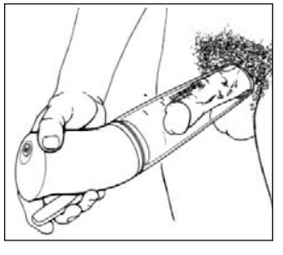
Step 3

Pump slowly to remove the air from the cylinder. Begin by pressing the pump handle two times to create the vacuum seal. Then wait 5 to 10 seconds between pumps to increase blood flow. You should not force the pump handle past its stopping point. If the vacuum pressure increases too quickly, you may feel discomfort.

If you have any discomfort, stop pumping and press the vacuum release button. Then begin pumping again. Continue slowly for best results, waiting 5 to 10 seconds between pumps. You may need to press the vacuum-release button several times while creating the erection. The number of pumps needed for a firm erection will vary according to the individual. Experiment to find out how many times you'll need to pump.

Step 4



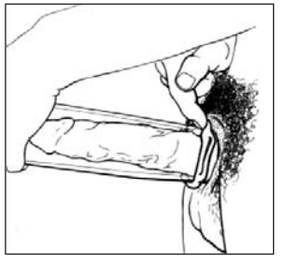
Usually the penis will lift slightly from the floor of the cylinder when the erection is complete. This process may take a few minutes. If your erection begins to press uncomfortably against the inside of the insert, remove the insert and start over without it.

NOTE: It may take a bit longer than expected for some men to get an erection. By repeating the practice sessions, you'll be able to get a firmer erection more quickly and be able to use less vacuum.

How to Keep the Erection – Manual Model

With the tension ring loaded on your cylinder, follow the steps you've learned already to create an erection using the System. Remember to use Osbon Personal Lubricant™ and to place the cylinder over your penis ensuring the "U" notch is to the bottom of the penis and the loops are to the top.

NOTE: If you are not sure if the ring is positioned correctly, remove the ring from the cylinder and repeat the ring loading steps.



Step 1

Slide the tension ring(s) from the cylinder to the base of your erect penis, one at a time. Keep the cylinder snug to the body while sliding off the ring(s). Many men find it easiest to slide the ring(s) off by pushing their fingers along the grooves in the cylinder.

Step 2

Press the green vacuum-release button and remove the cylinder. Set the cylinder aside during sexual activity. The penis will remain erect until you remove the tension ring(s). Do not leave the tension ring(s) on your penis longer than 30 minutes.

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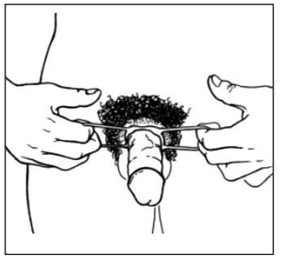
Removing the Tension Rings

Remove the tension ring(s) after sexual activity. Remember: Do not keep the ring(s) on your penis for longer than 30 minutes.



Step 1

Apply a small amount of lubricant in front of the ring, and on the penis.

Step 2

Grasp the loops and pull **SLIGHTLY** outward, away from the penis. Hold the loops outward for at least 10 seconds or until the penis loses some firmness.

Step 3

Slowly pull the ring(s) forward and off your penis.

ErecAid® Esteem® Vacuum Therapy System

Automatic Model

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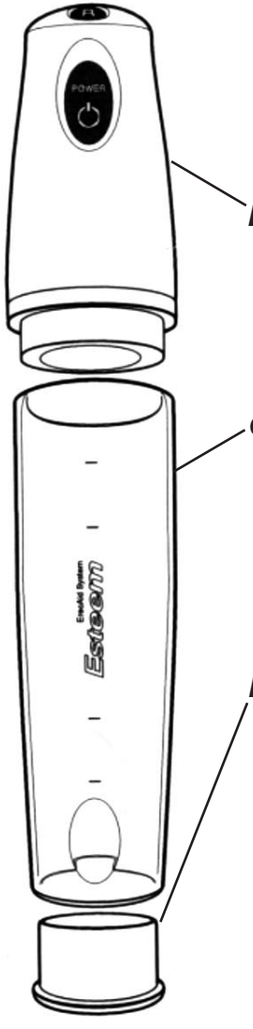
Components – Automatic Model

Study the diagram to become familiar with the name and purpose of each part of your new ErecAid Esteem System before you apply the device.



Pump

The automatic pump provides a simple, single touch method to create the proper vacuum.

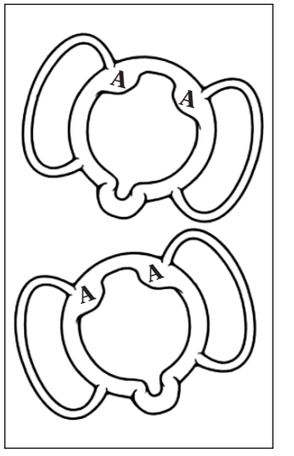
Cylinder

The oval end of the cylinder is designed so you can easily attach the automatic pump. The other end of the cylinder fits snugly against your body to help create the vacuum seal.

Insert

The insert may be used to decrease the diameter of the open end of the cylinder, if needed. You should try using the System with and without the insert to decide which way works best for you.

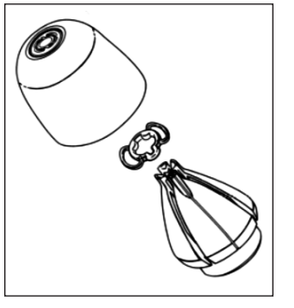
Pressure-Point™ Tension Rings



The patented pressure-point tension rings are medically engineered for safety, performance and comfort. You may use the rings individually or in various combinations to keep your erection once you have created it using the System *(refer to Situation on page 31)*. You will have four pressure-point tension rings packaged with your System: one Medium and one Large ring in standard tension (beige); one Medium and one Large ring in high tension (pink). *See Ring Tension Chart for tension and color details on page 22.*

NOTE: Please note that tension rings are a disposable item and will last 1-6 months or longer, depending on use and storage.

Easy-Action® Ring Applicator



The Easy-Action ring applicator is a specially designed tool that lets you easily load the Pressure-Point tension ring(s) onto your ErecAid Esteem System cylinder.

The Easy-Action ring applicator consists of two parts – a top part, or cap, and a bottom part, or cone.

Lubricant

Osbon Personal Lubricant™ plays an important part in the overall function of the System. Proper application of our water-soluble lubricant to the head of the penis and to the open end of the cylinder helps create a good vacuum seal against the body. The lubricant also helps you to load and remove the tension rings. You should use only water-based Osbon Personal Lubricant. **Other lubricants may damage the tension rings and other System parts, as well as void your limited lifetime warranty.**

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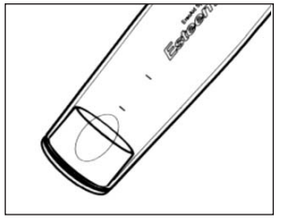
How to Assemble – Automatic Model

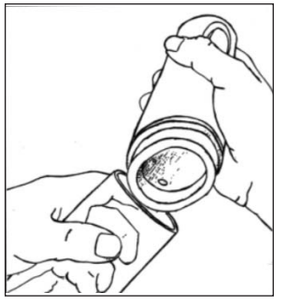
Step 1

Start with the insert in the smaller end of the cylinder, as packaged. The insert narrows the inside of the cylinder and keeps scrotal tissue from being drawn in while you create your erection. If your erection presses uncomfortably against the inside of the insert, remove the insert and use the cylinder without it.



Step 2

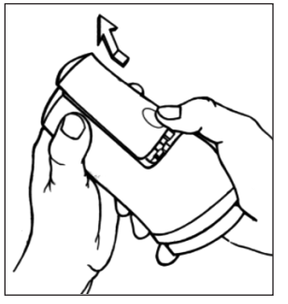
Attach the oval end of the pump to the large oval end of the cylinder by pressing them firmly together. Be sure to keep the cylinder's label face up and in line with the Power Button.



Now your ErecAid System is fully assembled, and you are ready to learn how to use the System.

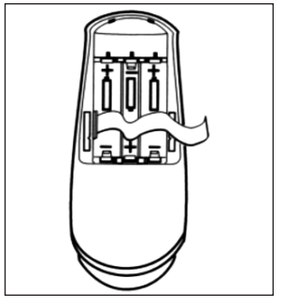
PLEASE NOTE: *Should you have difficulty attaching the pump to the cylinder, using your index finger, apply a small amount of lubricant to the outer rim of the pump. This will allow the cylinder to connect more easily.* ***Too much lubricant could cause it to seep into and damage the motor.***

How to Load the Batteries – Automatic Model



Step 1

The battery compartment door is located on the back of the pump. Remove the door by pressing firmly and sliding it towards the vacuum release button.



Step 2

Load the batteries to match the diagram inside the compartment. The System operates on three (3) AA-size batteries. Slide the battery compartment door back in place.

NOTE: Be sure to load your new batteries on top of the ribbon found in the compartment. By doing this, you can pull up on the ribbon to easily lift them out of the compartment when it is time for replacement.

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Practice Sessions – Automatic Model

Practice sessions should be **at least** 10–15 minutes daily for a **minimum** of two weeks.

Before using your ErecAid® System for intercourse, **you must practice** creating an erection. You will be much more satisfied with results by taking time to complete the practice sessions. Practice sessions help you learn your individual comfort level, the amount of vacuum you need and the most effective technique for getting a good seal and a firm erection.

Practice sessions also help you understand what to expect from the System, and the sessions can help you become more confident and more satisfied with your sexual experiences.

Most importantly, after a period of sexual inactivity, the vessels in the penis need to become accustomed to being filled with blood again. After a period of inactivity when the pump has not been utilized, practice sessions will again be necessary to recondition penile tissue prior to resuming sexual activity. If you will not be having sexual activity on a regular basis, you need to continue therapy practice sessions on a regular basis. Follow the practice session outlined below, you will provide a slow but steady increase of blood through the vessels of the penis, giving you a better erection.

During your initial practice sessions, **DO NOT** use a tension ring(s). You will only be practicing how to create an erection. Later, when you become comfortable with creating your erection, you will learn how to load and transfer tension rings. Proper use of the tension rings lets you keep a full erection suitable for intercourse.

During practice sessions skip to "How to Create an Erection" on page 25.

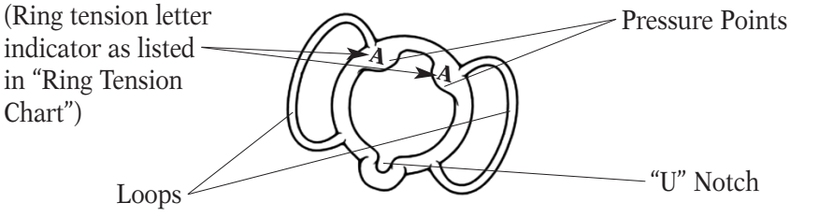
How to Select the Tension Ring

You will need to experiment to find the tension ring that's right for you. Begin with the largest Ring (A) and determine if it is comfortable and provides a satisfactory erection. If not, try the (B) Ring then and then the (C) Ring and then the (D) Ring. **Always try to keep the erection with the least amount of tension. Correct positioning of the tension ring is also necessary to keep the erection.** Tension rings should be positioned so that the "U" shaped notch is on the bottom of the penis and the pressure points are at the top of the penis.

NOTE: When using a combination of rings, the ring with the greatest amount of tension should be closest to your body. See page 31 for instructions on loading and transferring no more than two tension rings.

COLOR CODED TENSION RINGS

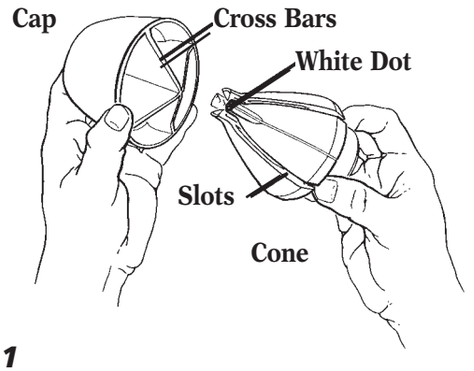
BEIGE	**PINK**
Standard Tension	**High Tension**

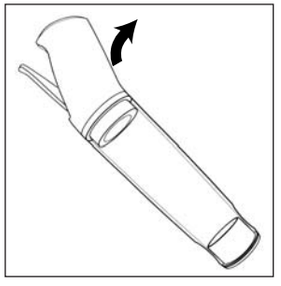


Ring Tension Chart

Minimum Tension	***Level One***	**One large standard-tension ring (beige-A)**
	Level Two	**One large high-tension ring (pink-B)**
	Level Three	**One medium standard-tension ring (beige-C)**
	Level Four	**One medium high-tension ring (pink-D)**
	Level Five	**One medium standard-tension (beige-C) and One large standard-tension ring (beige-A)**
	Level Six	**One medium high-tension (pink-D) and One large high-tension ring (pink-B)**
Maximum Tension	***Level Seven***	**One medium high-tension (pink-D) and One medium standard-tension ring (beige-C)**

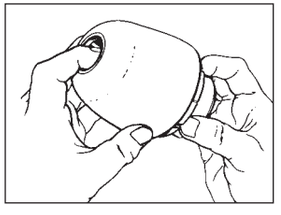
How to Load the Tension Ring Using the Easy-Action® Ring Applicator





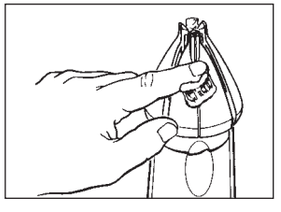
Step 1

Remove the pump and the insert from the cylinder. Put a towel on a table or counter top and stand the cylinder on top of the towel with the large end of the cylinder face down. The towel will keep the cylinder from slipping.



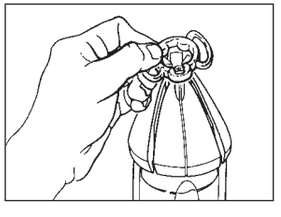
Step 2

Separate the Easy-Action ring applicator by holding the base of the cone in your hand and then pushing the button on the top of the cap. Place the base of the ring applicator cone in the small open end of the cylinder. Twist the cone so that the white dot on top of the cone lines up with the cylinder groove **opposite** the cylinder label.



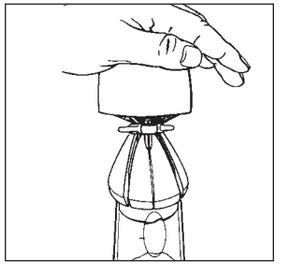
Step 3

Lubricate the entire cone surface with Osbon Personal Lubricant.™



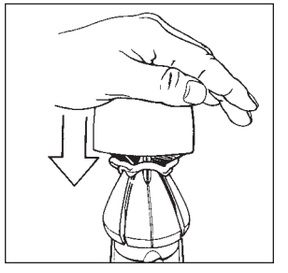
Step 4

Place the tension ring on the cone, making sure to align the **U-notch** on the tension ring with the **white dot** on the cone.



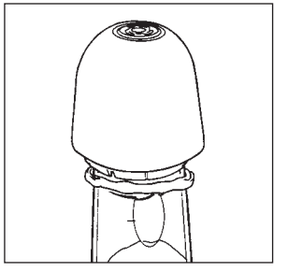
Step 5

Place the cap back on the cone and tension ring, lining up the cross bars of the underside of the cap with the slots on the top of the cone.



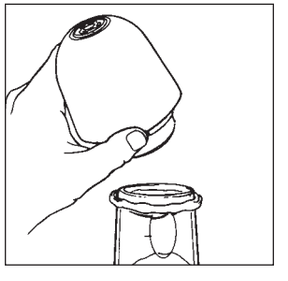
Step 6

Then quickly and firmly press straight down on the cap of the ring applicator with one hand while holding the cylinder in an upright position on the towel with your other hand to help stabilize it.



Step 7

The tension ring should now be transferred to the cylinder in the correct position. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump end of the cylinder to allow space for the additional ring(s). Then, choose another ring and repeat steps 2 through 6.



Step 8

After you have loaded your tension ring(s), remove your ring applicator from the cylinder and replace the insert. Place the pump handle back on to the cylinder. You are now ready to create an erection with your ErecAid® Esteem® System.

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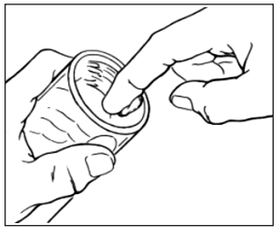
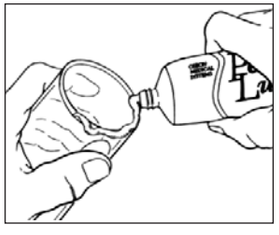
How to Create an Erection – Automatic Model

Assemble your System according to the two-step procedure on page 19.





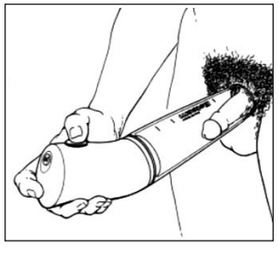
Step 1

Apply Osbon Personal Lubricant™ to the following:

1. **two inches inside the open end of the cylinder;**
2. **the rim of the cylinder which meets the body to form the vacuum seal; and**
3. **the entire head of the penis.**

Applying lubricant properly will help you achieve the best erection possible.

Tip: *Trimming the pubic hair around the base of the penis with a pair of scissors may also prove helpful in creating an airtight seal.*

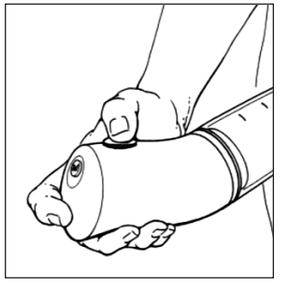


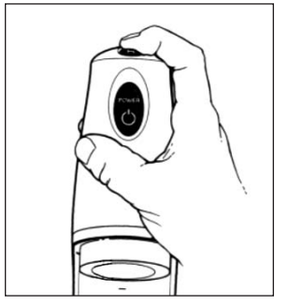
Step 2

It is recommended that you stand for this step (the System can also be used when you are sitting or lying down).

Place the lubricated penis inside the cylinder with the label on the cylinder facing up. With one hand, hold the cylinder at a downward 45° angle with the open end snugly against the body.

Tip: *Rotate cylinder slightly back and forth to make an airtight seal against the body, make sure the testicles are not drawn into the cylinder.*



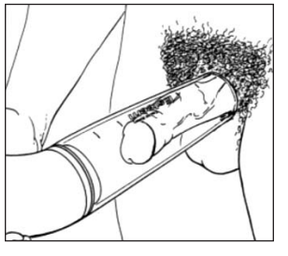


Step 3

Press the power button on the pump to remove the air from the cylinder. Now begin creating the vacuum by pressing the power button on the pump for several seconds. Then stop the pump and wait 5 to 10 seconds to increase blood flow. If the vacuum pressure increases too quickly, you may feel discomfort.

If you have any discomfort, stop the pump and press the vacuum-release button. Then turn the pump on again for several seconds. Rather than running the pump continually, it is recommended that the pump be turned on for several seconds then turned off for 5 to 10 seconds.

Continue this until you have achieved an erection. You may need to press the vacuum-release button several times. The amount of vacuum needed for a firm erection will vary according to the individual. Experiment to find out how long you'll need to keep the pump running.



Step 4

Usually the penis will lift slightly from the floor of the cylinder when the erection is complete. This process may take a few minutes. If your erection begins to press uncomfortably against the inside of the insert, remove the insert and start over without it.

NOTE: It may take a bit longer than expected for some men to get an erection. By repeating the practice sessions, you'll be able to get a firmer erection more quickly and be able to use less vacuum.

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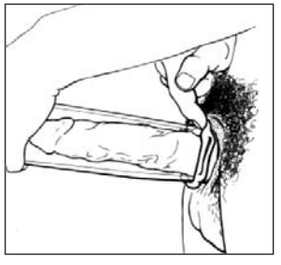
How to Keep the Erection – Automatic Model

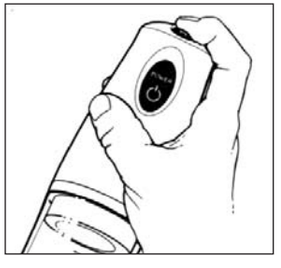
With the tension ring loaded on your cylinder, follow the steps you've learned already to create an erection using the System. Remember to use Osbon Personal Lubricant™ and to place the cylinder over your penis ensuring the "U" notch is to the bottom of the penis and the loops are to the top.

NOTE: If you are not sure if the ring is positioned correctly, remove the ring from the cylinder and repeat the ring loading steps.



Step 1

Slide the tension ring(s) from the cylinder to the base of your erect penis, one at a time. Keep the cylinder snug to the body while sliding off the ring(s). Many men find it easiest to slide the ring(s) off by pushing their fingers along the grooves in the cylinder.

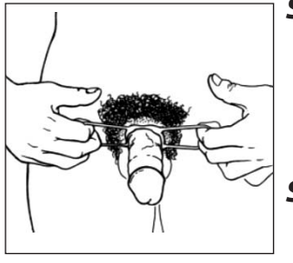


Step 2

Press the green vacuum-release button and remove the cylinder. Set the cylinder aside during sexual activity. The penis will remain erect until you remove the tension ring(s). Do not leave the tension ring(s) on your penis longer than 30 minutes.

Removing the Tension Rings

Remove the tension ring(s) after sexual activity. Remember: Do not keep the ring(s) on your penis for longer than 30 minutes.



Step 1

Apply a small amount of lubricant in front of the ring, and on the penis.

Step 2

Grasp the loops and pull **SLIGHTLY** outward, away from the penis. Hold for at least 10 seconds or until the penis loses some firmness.

Step 3

Slowly pull the ring(s) forward and off your penis.

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Tips for Best Results

1. Be sure the cylinder is firm against your body. If you allow air to enter the cylinder, the vacuum will not be sufficient to create an erection. If getting a good seal is difficult for you, use a pair of scissors to trim your pubic hair around the base of the penis so the cylinder can make better contact with your skin. Remember to apply lubricant to the rim of the cylinder. The lubricant is designed to help create a proper seal.
2. Allow your erection to develop slowly. Increasing the vacuum too quickly may cause discomfort or temporary bruising.
3. If you lose your erection after you transfer the tension ring(s), you may need to increase the amount of tension. Refer to the chart on page 17 to select the best tension for you.
4. You may also lose the erection if air enters the cylinder before the tension ring(s) is in place. Be sure you position the tension ring(s) on the penis before releasing the vacuum. Keep the cylinder pressed firmly to your body during transfer of the tension ring(s).
5. **Be sure to remove the tension ring(s) within 30 minutes.** Do not fall asleep with the tension ring(s) in place. Remove the tension ring(s) before urinating.
6. An erection achieved with the System usually has greater girth (thickness), since the blood vessels are filled to their maximum potential. However, ErecAid Esteem System is not an enlargement device; it simply allows the penis to obtain its largest natural state.
7. Keep in mind that an erection achieved with the System will remain rigid until you remove the tension ring(s). Most men are able to continue intercourse after ejaculation/orgasm, if desired.

NOTE: *For automatic model, be sure the batteries are in good working order before applying the System. Insufficient power may not provide enough vacuum to create an erection. Be sure to remove batteries if anticipating an extended period between applications of the System. Whenever you turn off the automatic pump, be sure to press the vacuum-release button briefly before restarting the pump motor.*

Situations and Recommendations

Just as there are many causes of Erectile Dysfunction, many different situations may occur with its management. Some situations may require special attention as you use ErecAid® Esteem® System. If you encounter any of the situations described on the following pages, follow the recommendations outlined to achieve a comfortable erection with your ErecAid System.

This information is not intended to take the place of medical advice from your prescribing physician.

Situation – Erection Not Suitable for Intercourse

You have used the pump and cylinder to obtain an erection, but have not achieved an erection suitable for intercourse.

Recommendation

1. Liberally lubricate the head of your penis, two inches (5 cm) inside the open end of the cylinder and the rim of the cylinder, as previously described.
2. Place the lubricated penis into the cylinder. Pump slowly, pausing for 5 to 10 seconds between pumps.
3. If the penis starts to tingle or feels uncomfortable while pumping, push the vacuum-release button until that particular feeling goes away. Resume pumping until the uncomfortable feeling starts again or until you achieve an erection.
4. Release the vacuum, allowing the penis to become soft. Without removing the cylinder, repeat steps two and three.

Practice this process 10 to 15 minutes daily without the tension ring(s) (see page 8 or page 21 Practice Sessions) until you can achieve and maintain an erection within the cylinder. Repeat for a minimum of two weeks.

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Situation – Initial Loss of Firmness

You lose firmness when you transfer the tension ring(s).

Recommendation

Reapply vacuum with ring(s) still in place. Be sure you have adequately lubricated the cylinder. Place cylinder over your partially erect penis and tension ring(s). Hold the cylinder firmly against the body. Then slowly pump a few additional times until you achieve sufficient firmness.

Situation – Loss of Firmness During Sexual Activity

You have used each of the tension rings individually but still lose firmness during sexual activity. In other words, Tension Levels 1–4 (described on pages 9 & 22) have not provided sufficient firmness.

Recommendation

Remove the single tension ring from the penis. Follow the steps below to position and transfer no more than two tension rings.

1. Begin with one medium and one large standard-tension ring (Tension Level 5, described on pages 9 & 22). Continue adjusting ring tension up to Tension Level 7 until sufficient firmness is achieved. Once the optimal combination of rings is in place at the base of the erect penis, DO NOT adjust them or firmness will be lost.
2. Position the ring with the greater amount of tension on the cylinder first. Once loaded on the cylinder, slide the first ring 3/4" away from the end of the cylinder to allow room for the second ring.
3. Position the second ring on the cylinder and recreate the erection.
4. Transfer the first ring (lowest tension) onto the base of your penis – this will break the vacuum seal.
5. Twist the cylinder slightly to move it over the applied ring and re-create the vacuum. The first ring will now be inside the cylinder. *NOTE: If you are using the insert, remove it completely to reposition the cylinder over the tension ring on the penis.*
6. Re-create the vacuum until the penis again lifts from the floor of the cylinder. Transfer the second ring onto the base of the penis, so that it leap frogs over the first ring and is closest to the body.
7. If you continue to lose firmness during sexual activity after trying all seven tension levels outlined on pages 9 & 22, call Timm Medical Technologies, Inc.'s Technical Support for assistance.

Situation – Scrotal Tissue Pulled into Cylinder

The force of the vacuum pulls body or scrotal tissue into the cylinder.

Recommendation

1. Remember to pump slowly.
2. Try using the optional adapter insert.
3. In the beginning, do not apply lubricant to the rim area of the cylinder that comes into contact with scrotal tissue. However, if you find that you need to apply lubricant to the entire rim to get an airtight seal, be sure to wipe off any excess lubrication from around the scrotal sac.
4. Make sure the underside of the penis is in contact with the floor of the cylinder. Reach underneath the cylinder with a dry cloth and gently remove the scrotal tissue from the cylinder. If you lose pressure, pump a few more times.
5. If these steps do not solve the issue, an EZ™ Tension Ring will need to be purchased.

NOTE: Call Timm Medical Technologies, Inc.'s Technical Support for assistance and information about optional EZ Tension Rings at 800-438-8592.

Situation – Erect Penis has Distortion or Curvature

While using your ErecAid Esteem system, you discover that the erect penis has a distortion or curvature.

Recommendation

If you notice a distortion, bend or curve in your penis when you first use your ErecAid system, discontinue use and seek your physician's advice. Some men who have not been sexually active for some time may have Peyronie's Disease. See Glossary for definition.

Situation – Unable to Release Vacuum

You have achieved an erection and the release button does not release pressure.

Recommendation

1. Press and hold release button.
2. Place one finger between the cylinder and body to manually release vacuum.

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Don't Worry If . . .

…You feel pressure while applying the vacuum. This is not harmful. If you feel discomfort, however, it may be a signal that you are pumping too fast. Simply press the vacuum-release button, wait a moment and begin again.

…Your penis turns slightly dusky or bluish in color after you apply the tension ring(s). This is a normal response to the increase of blood in the penis. The discoloration should disappear when you remove the tension ring(s).

…You experience some petechiae (very tiny reddish spots beneath the skin) or bruising of the penis when you first begin using your System. This is a response to placing the penis under vacuum pressure too long, too quickly or after a long period of inactivity. If this happens, discontinue use of the System until discoloration completely disappears – about five to seven days.

…You notice a slight drop in the temperature of the penis. This coolness is not harmful. It is a normal response to the reduced blood flow caused by the tension ring. It is possible to warm your penis by wrapping a warm washcloth around it for several moments.

…Your erection has a "hinge" effect. The penis may pivot at its base when the ring is in place. If this occurs, you may find it necessary to guide the penis into the vagina or try different positions with your partner for successful intercourse.

…Your semen does not flow through at point of climax. The pressure of the tension ring(s) sometimes interferes with ejaculation. This is not harmful, and does not affect climax. Instead, your semen may flow out when you remove the tension ring(s). (Note: Tension rings are NOT a means of contraception.)

…Your cylinder develops condensation on the inside. This is simply the result of the heat from your body reacting with the lubricant. (Note: This "fogging" can be reduced by running warm water over your cylinder and then drying it before you use the System.)

System Care

After each use, carefully clean and store the System as follows:

1. Remove the vacuum pump and the insert, if used, from the cylinder. Separate the Easy-Action® ring applicator into its two parts, being sure the cap button remains depressed.
2. Wipe the pump with a damp cloth. Never wash or immerse the pump in water.
3. Wash cylinder, insert, tension ring(s) and ring applicator with warm, soapy water. **Never place any ErecAid® component in dishwasher or microwave.** We recommend that you use liquid soap when cleaning your System. Rinse thoroughly.
4. Let all the parts air-dry thoroughly in a ventilated place before storing. Be sure to store the System unassembled.

Glossary of Terms

ERECTILE DYSFUNCTION (ED) the inability to get and keep a penile erection suitable for sexual intercourse.

ERECTION the bodily process in males which fills and stores blood in the penis, making it rigid.

IMPOTENCE a common name for Erectile Dysfunction.

PETECHIAE tiny, round purplish-red spots caused by broken or swollen blood vessels just beneath the surface of the skin.

PEYRONIE'S DISEASE a condition in which the penis curves or bends abnormally due to a build-up of scar tissue inside the penis.

PRIAPISM an erection that lasts more than four hours; an abnormally prolonged erection.

SCROTUM the soft pouch or sac at the base of the penis which contains the testes.

URETHRAL STRICTURE scar tissue inside the penile urination channel which may cause the channel to narrow, blocking the flow of urine and/or semen.

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90-Day Return Policy

SPECIAL NOTE
This refund policy is affected at the original point of purchase.
The following return policy is designed to protect and serve your recent purchase of Timm Medical Technologies, Inc. ErecAid® Esteem® System.

PURCHASED DIRECTLY FROM Timm Medical Technologies, Inc.
Timm Medical Technologies, Inc. provides a 90-day return policy on systems purchased directly from Timm Medical Technologies, Inc. If the system fails to produce the desired results within 90 days, you may qualify for a refund. **To qualify for a refund, you must complete the following steps;**

1) have completed and mailed the ErecAid® Esteem® Warranty Registration Card from your System Kit;
2) call and receive instruction from a Timm Medical Technologies, Inc.'s Support Service advisor at least twice;
3) meet and work with a Timm Medical Technologies, Inc.'s Clinical Technician at the prescribing physician's office, when geographically feasible;
4) obtain a Return Authorization Number (RMA) from Technical Support Services, and return **all** System components, booklets and video within four weeks of receiving your Return Authorization Number (RMA). Any system sent to Timm Medical Technologies, Inc. without a RMA number will be returned to sender without a refund being processed.

The 90-day return policy is only available for Systems purchased directly from Timm Medical Technologies, Inc. and is only available to the System's original owner. The return policy does not apply to any subsequent System purchase or components. This policy is in place of any other policies expressed or implied.

PURCHASED FROM another vendor and NOT Timm Medical Technologies, Inc.
Please contact the vendor (e.g. store, pharmacy, doctor's office) with regards to their particular refund and return policies.

NOTE: The above Return Policy is subject to change without notice.

Notes and Cautions

This symbol means: Attention, consult accompanying documents.

This symbol indicates Type BF equipment.

This symbol indicates that the ErecAid Automatic System should be disposed of properly according to your local laws on regulation.

CAUTIONS:

This device is not intended for use in the presence of flammable mixtures.

This device requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

This device may be affected by portable and mobile RF communications equipment.

This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Esteem Automatic should be observed to verify normal operation.

NOTE ON CLASSIFICATION:

This device is classified as internally powered.

This device is classified Type BF equipment for protection against electrical shock.

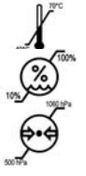
This device is classified as ordinary equipment without protection against ingress of water.

This device is classified as suitable for continuous operation.

NOTE ON DISPOSAL:

This device contains electronic components and should be disposed of according to local, state and national regulations. Please contact your local authorities for proper disposal of small electronics devices. Remove batteries and recycle them according to regulations as well. Many retail outlets that sell batteries provide for free recycling.

NOTE ON TRANSPORT AND STORAGE:


Ambient temperature range: -40°C to +70°C
Relative humidity range: 10% to 100%, including condensation
Atmospheric pressure range: 500hPa to 1060 hPa.

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Guidance and manufacturer's declaration – electromagnetic emissions

The Esteem Automatic is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem Automatic should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Esteem Automatic uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Esteem Automatic is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The Esteem Automatic is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem Automatic should assure that it is used in such an environment.

IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Esteem Automatic requires continued operation during power mains interruptions, it is recommended that the Esteem Automatic be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

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Guidance and manufacturer's declaration – electromagnetic immunity

The Esteem Automatic is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem Automatic should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Esteem Automatic, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	d = 1.2√P d = 1.2√P 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 2.3√P 800 MHz to 2.3 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Esteem Automatic is used exceeds the applicable RF compliance level above, the Esteem Automatic should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Esteem Automatic.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Esteem Automatic

The Esteem Automatic is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Esteem Automatic can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Esteem Automatic as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of 150 kHz to 80 MHz W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2 P	80 MHz to 800 MHz d = 1.2 P	800 MHz to 2.5 GHz d = 2.3 P
0.01	.12m	.12m	.23m
0.1	.38m	.38m	.76m
1	1.2m	1.2m	2.3m
10	3.8m	3.8m	7.6m
100	12m	012m	23m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN OBTAIN ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY. If you have any questions about this notice, please contact Privacy Officer of our office at Timm Medical Technologies, Inc., 6585 City West Parkway, Eden Prairie, MN 55344, toll free (800) 438-8592.

WHO WILL FOLLOW THIS NOTICE

This notice describes the information privacy practices followed by our employees, staff and other office personnel. The practices described in this notice will also be followed by health care providers you consult with by telephone (when your regular health care provider from our office is not available) who provide "call coverage" for your health care provider.

YOUR HEALTH INFORMATION

This notice applies to the information and records we have about your health, health status, and the health care and services you receive at this office. We are required by law to give you this notice. It will tell you about the ways in which we may use and disclose health information about you and describes your rights and our obligations regarding the use and disclosure of that information.

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Notice of Privacy Practices *(continued)*

HOW WE MAY USE AND DISCLOSE HEALTH INFORMATION ABOUT YOU

For Treatment We may use health information about you to provide you with medical treatment or services. We may disclose health information about you to doctors, nurses, technicians, office staff or other personnel who are involved in taking care of you and your health. For example, your doctor may be treating you for a heart condition and may need to know if you have other health problems that could complicate your treatment. The doctor may use your medical history to decide what treatment is best for you. The doctor may also tell another doctor about your condition so that doctor can help determine the most appropriate care for you.

Different personnel in our office may share information about you and disclose information to people who do not work in our office in order to coordinate your care, such as phoning in prescriptions to your pharmacy, scheduling lab work and ordering x-rays. Family members and other health care providers may be part of your medical care outside this office and may require information about you that we have.

For Payment We may use and disclose health information about you so that the treatment and services you receive at this office may be billed to and payment may be collected from you, an insurance company or a third party. For example, we may need to give your health plan information about a service you received here so your health plan will pay us or reimburse you for the service. We may also tell your health plan about a treatment you are going to receive to obtain prior approval, or to determine whether your plan will cover the treatment.

For Health Care Operations We may use and disclose health information about you in order to run the office and make sure that you and our other patients receive quality care. For example, we may use your health information to evaluate the performance of our staff in caring for you. We may also use health information about all or many of our patients to help us decide what additional services we should offer, how we can become more efficient, or whether certain new treatments are effective.

Appointment Reminders We may contact you as a reminder that you have an appointment for treatment or medical care at the office.

Treatment Alternatives We may tell you about or recommend possible treatment options or alternatives that may be of interest to you.

Health-Related Products and Services We may tell you about health-related products or services that may be of interest to you.

Please notify us if you do not wish to be contacted for appointment reminders, or if you do not wish to receive communications about treatment alternatives or health-related products and services. If you advise us in writing (at the address listed at the top of this Notice) that you do not wish to receive such communications, we will not use or disclose your information for these purposes.

SPECIAL SITUATIONS

We may use or disclose health information about you without your permission for the following purposes, subject to all applicable legal requirements and limitations:

To Avert a Serious Threat to Health or Safety We may use and disclose health information about you when necessary to prevent a serious threat to your health and safety or the health and safety of the public or another person.

Required By Law We will disclose health information about you when required to do so by federal, state or local law.

Research We may use and disclose health information about you for research projects that are subject to a special approval process. We will ask you for your permission if the researcher will have access to your name, address or other information that reveals who you are, or will be involved in your care at the office.

Organ and Tissue Donation If you are an organ donor, we may release health information to organizations that handle organ procurement or organ, eye or tissue transplantation or to an organ donation bank, as necessary to facilitate such donation and transplantation.

Military, Veterans, National Security and Intelligence If you are or were a member of the armed forces, or part of the national security or intelligence communities, we may be required by military

Notice of Privacy Practices *(continued)*

command or other government authorities to release health information about you. We may also release information about foreign military personnel to the appropriate foreign military authority.

Workers' Compensation We may release health information about you for workers' compensation or similar programs. These programs provide benefits for work-related injuries or illness.

Public Health Risks We may disclose health information about you for public health reasons in order to prevent or control disease, injury or disability; or report births, deaths, suspected abuse or neglect, non-accidental physical injuries, reactions to medications or problems with products.

Health Oversight Activities We may disclose health information to a health oversight agency for audits, investigations, inspections, or licensing purposes. These disclosures may be necessary for certain state and federal agencies to monitor the health care system, government programs, and compliance with civil rights laws.

Lawsuits and Disputes If you are involved in a lawsuit or a dispute, we may disclose health information about you in response to a court or administrative order. Subject to all applicable legal requirements, we may also disclose health information about you in response to a subpoena.

Law Enforcement We may release health information if asked to do so by a law enforcement official in response to a court order, subpoena, warrant, summons or similar process, subject to all applicable legal requirements.

Coroners, Medical Examiners and Funeral Directors We may release health information to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death.

Information Not Personally Identifiable We may use or disclose health information about you in a way that does not personally identify you or reveal who you are.

Family and Friends We may disclose health information about you to your family members or friends if we obtain your verbal agreement to do so or if we give you an opportunity to object to such a disclosure and you do not raise an objection. We may also disclose health information to your family or friends if we can infer from the circumstances, based on our professional judgment that you would not object. For example, we may assume you agree to our disclosure of your personal health information to your spouse when you bring your spouse with you into the exam room during treatment or while treatment is discussed.

OTHER USES AND DISCLOSURES OF HEALTH INFORMATION

We will not use or disclose your health information for any purpose other than those identified in the previous sections without your specific, written Authorization. If you give us Authorization to use or disclose health information about you, you may revoke that Authorization, in writing, at any time. If you revoke your Authorization, we will no longer use or disclose information about you for the reasons covered by your written Authorization, but we cannot take back any uses or disclosures already made with your permission.

If we have HIV or substance abuse information about you, we cannot release that information without a special signed, written authorization from you that complies with the law governing HIV or substance abuse records.

YOUR RIGHTS REGARDING HEALTH INFORMATION ABOUT YOU

You have the following rights regarding health information we maintain about you:

Right to Inspect and Copy You have the right to inspect and copy your health information, such as medical and billing records, that we use to make decisions about your care. You must submit a written request to Privacy Office at Timm Medical Technologies, Inc. in order to inspect and/or copy your health information. If you request a copy of the information, we may charge a fee for the costs of copying, mailing or other associated supplies. We may deny your request to inspect and/or copy in certain limited circumstances. If you are denied access to your health information, you may ask that the denial be reviewed. If such a review is required by law, we will select a licensed health care professional to review your request and our denial. The person conducting the review will not be the person who denied your request, and we will comply with the outcome of the review.

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Notice of Privacy Practices *(continued)*

Right to Amend If you believe health information we have about you is incorrect or incomplete, you may ask us to amend the information. You have the right to request an amendment as long as the information is kept by this office.

We may deny your request for an amendment if it is not in writing or does not include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- **a)** We did not create, unless the person or entity that created the information is no longer available to make the amendment.
- **b)** Is not part of the health information that we keep.
- **c)** You would not be permitted to inspect and copy.
- **d)** Is accurate and complete.

Right to an Accounting of Disclosures You have the right to request an "accounting of disclosures." This is a list of the disclosures we made of medical information about you for purposes other than treatment, payment and health care operations. To obtain this list, you must submit your request in writing to Privacy Officer. It must state a time period, which may not be longer than six years and may not include dates before April 14, 2003. Your request should indicate in what form you want the list (for example, on paper, electronically). We may charge you for the costs of providing the list. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

Right to Request Restrictions You have the right to request a restriction or limitation on the health information we use or disclose about you for treatment, payment or health care operations. You also have the right to request a limit on the health information we disclose about you to someone who is involved in your care or the payment for it, like a family member or friend. For example, you could ask that we not use or disclose information about a surgery you had.

We are Not Required to Agree to Your Request If we do agree, we will comply with your request unless the information is needed to provide you emergency treatment.

To request restrictions, you may complete and submit a Request For Restricting Uses and Disclosures and Confidential Communications Form Information to: Privacy Officer, Timm Medical Technologies, Inc., 6585 City West Parkway, Eden Prairie MN 55344.

Right to Request Confidential Communications You have the right to request that we communicate with you about medical matters in a certain way or at a certain location. For example, you can ask that we only contact you at work or by mail.

To request confidential communications, you may complete and submit the Requests For Restricting Uses and Disclosures and Confidential Communications to Privacy Officer. We will not ask you the reason for your request. We will accommodate all reasonable requests. Your request must specify how or where you wish to be contacted.

Right to a Paper Copy of This Notice You have the right to a paper copy of this notice. You may ask us to give you a copy of this notice at any time. Even if you have agreed to receive it electronically, you are still entitled to a paper copy. To obtain such a copy, contact Privacy Officer, Timm Medical Technologies, Inc., 6585 City West Parkway, Eden Prairie MN 55344.

CHANGES TO THIS NOTICE

We reserve the right to change this notice, and to make the revised or changed notice effective for medical information we already have about you as well as any information we receive in the future. We will post a summary of the current notice in the office with its effective date in the top right hand corner. You are entitled to a copy of the notice currently in effect.

COMPLAINTS

If you believe your privacy rights have been violated, you may file a complaint with our office or with the Secretary of the Department of Health and Human Services. To file a complaint with our office, contact Privacy Officer, Timm Medical Technologies, Inc., 6585 City West Parkway, Eden Prairie MN 55344 or call toll free: (800) 438-8592. You will not be penalized for filing a complaint.

ErecAid® Esteem® Warranty Registration Card

To register please complete, fold, seal, and mail this form within 90 days of purchase, or go to www.timmmedical.com to register on-line.

Indicate Model: ❑ **Manual** ❑ **Automatic (Battery)**

Print or Type Name _____

Address _____

City _____ **State** _____ **Zip** _____

Province/Country _____ Postal Code _____
(If other than U.S.)

Telephone No. (_____) _____ Date of Birth _____

Place Purchased _____ **Date Purchased** _____

Email Address _____

Do you wish to receive future information from Timm Medical Technologies? Yes ❑ No ❑

Signature _____ Date _____

Prescribing Physician's Name _____

Medical Specialty: ❑ Urology ❑ Family Medicine ❑ Internal Medicine ❑ Other

Physician's Address _____

City _____ State _____ Zip _____

Province/Country _____ Postal Code _____
(If other than U.S.)

Telephone No. (_____) _____

By returning this Warranty Registration Card I acknowledge receipt of the ErecAid System and User Guide. The User Guide includes the Notice of Privacy Practices disclosure.

REGISTER WITHIN 90 DAYS OF PURCHASE TO RECEIVE THE FOLLOWING BENEFITS:

- Limited Lifetime Warranty
- Refund Options
- Toll-free Technical Assistance

REGISTRATION NUMBER:

Timm Medical Technologies, Inc.
6585 City West Parkway
Eden Prairie, MN 55344 USA
Toll Free: 800-438-8592
Phone: 952-947-9410
Fax: 952-947-9411
www.timmmedical.com

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TIMM MEDICAL TECHNOLOGIES
6585 CITY WEST PKWY
EDEN PRAIRIE, MN 55344-9831

For Further Assistance

If you still have questions on the application of your new ErecAid® Esteem® System after reading this Guide and viewing your video, call **Timm Medical Technologies, Inc.'s Technical Support, available 24 hours a day, seven days a week. Call toll-free 800-438-8592 and ask for Technical Support Services. International owners should contact the local ErecAid System distributor.**

When you call Technical Support Services, you will have a private conversation with a trained professional who has earned accredited certification in vacuum therapy training with ErecAid Esteem System. If you have a problem that requires medical attention, they will direct you to speak with a physician.

Limited Lifetime Warranty

Timm Medical Technologies, Inc. protects the major components of your ErecAid Esteem System with a limited lifetime replacement warranty. This means that we will repair or replace the cylinder and pump free of charge if they ever fail due to defective workmanship or materials for the lifetime of the product (as determined by Timm Medical Technologies, Inc.). The limited lifetime warranty is granted only to the original registered owner of the System and requires return of the damaged or defective component. The limited lifetime warranty does not cover accessory items such as tension rings, the inserts, ring applicator, lubricant or carrying case. **Your System must be registered within 90 days of purchase in order to activate the limited lifetime warranty.** This limited lifetime warranty is in place of any other warranties expressed or implied.